

October 27, 1999

VETERINARY SERVICES MEMORANDUM NO. 800.76

Subject: Trade Names and Logos on Labels of Licensed Veterinary
Biological Products

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

I. PURPOSE

This memorandum provides guidance concerning the use of promotional designs and devices such as trade names and logos on labeling of licensed veterinary biological products which is consistent with the intent and purpose of the Virus-Serum-Toxin Act and the regulations in 9 CFR 112.4(c) and 112.4(d).

II. CANCELLATION

This memorandum cancels Veterinary Services Memorandum No. 800.76 dated January 7, 1986.

III. BACKGROUND

This memorandum clarifies the intent of the Virus-Serum-Toxin Act and the regulations to ensure that products will be labeled in a manner that ensures their safety and efficacy. The regulations in 9 CFR 102.4 and 112.1 specify that labeling may not be false or misleading in any particular. The label should not leave the user of the product with a false or misleading impression regarding the origin or identity of the product or regarding other factors pertinent to the product. The Center for Veterinary Biologics (CVB) considers labels which could create such an impression to be false or misleading and does not allow their use.

The regulations in 9 CFR 112.4 place certain restrictions on the use of trade names, logos, package designs, and other devices placed on product labels to help ensure these labels are not false or misleading. CVB considers designs which indicate or give the impression that a distributor or permittee is the manufacturer of a veterinary biologic to be sufficiently false or misleading to pose a potential risk to the user and prohibits their use. CVB also prohibits nonexclusive use of trade names on products which could create uncertainty as to the identity of the manufacturer or product characteristics.

IV. GUIDELINES

A. Trade Names

1. *Restriction of Use* - Except as otherwise provided, associate a trade name with a single product.

2. *Right to Use* - A manufacturer, distributor, or permittee must have exclusive right—by ownership, assignment, exclusive-use license, or by other means—to use a trade name on a product.

3. *Transfer for Use* - A distributor or permittee that owns exclusive right to a trade name may transfer the trade name to a manufacturer for use on the labeling of a substantially similar product for such distributor or permittee.

4. *Determining “Substantially Similar”* - The Center for Veterinary Biologics-Licensing and Policy Development (CVB-LPD) will make a determination of whether a product is “substantially similar” on a case-by-case basis. CVB-LPD may require the new manufacturer to add a postscript to the trade name (trade name+x) where, in their opinion, the change of manufacturer creates a product which is substantially similar but not identical with respect to a factor which could pose a potential risk to users.

B. Logos

Firms may use a distributor’s or permittee’s logo on labeling provided that such use does not create the impression or appearance, when the label is considered in its entirety, that the distributor or permittee is the manufacturer. See Veterinary Services Memorandum No. 800.80 for additional guidelines on Distributor Labels.

/s/ Thomas E. Walton for

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